

**CODES AND STANDARDS APPLICABLE TO
QUALITY MANAGEMENT AND
QUALITY ASSURANCE**

A Partial Annotated List

CODE OF FEDERAL REGULATIONS (CFR):

10 CFR 50, *Domestic Licensing of Production Facilities*

Contains Nuclear Regulatory Commission (NRC) regulations for licensing production and user facilities. Also describes requirements for subcontractors and vendors for nuclear facilities.

10 CFR 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*

Provides quality assurance requirements for the design, construction, and operation of nuclear power and fuel-reprocessing plants.

10 CFR 71, *Type Quantities of Radioactive Material*

Establishes requirements for preparing, packaging, and transporting nuclear materials. Specifically contains procedures for packaging and shipping fissile material and radioactive materials in excess of Type A quantities.

10 CFR 830, *Nuclear Safety Management*

Institutes safety requirements to prevent the uncontrolled release of radioactivity into the environment; to prevent inadvertent criticality; to monitor and limit facility staff exposure to radiation and radioactivity; and to protect the public from exposure to radiation and radioactive contamination. Supersedes DOE Orders for nuclear facilities.

10 CFR 830.120, *Quality Assurance Requirements*

Mandates the development and implementation of a formalized quality assurance program addressing the three functional areas that affect quality: management, performance, and assessment.

DEPARTMENT OF DEFENSE (DOD):

MIL-Q9858A, *Quality Program Requirements*

Used as a standard by the armed services. Applies to purchased equipment, systems, and services.

MIL-STD-45662A, *Calibration Systems Requirements*

Applies to all contracts in which measuring and test equipment or measurement standards are used. Establishes requirements for implementing and maintaining a calibration program for measuring and test equipment used by the military.

MIL-I-45208A, *Inspection System Requirements*

Establishes requirements for contractors' inspection systems. Applies to all suppliers or services referenced in specifications, contracts, or orders. Requires government inspection of materials before they are shipped by the contractor.

MIL-STD-105D, *Sampling Procedures and Tables for Inspection by Attributes*

Used primarily for inspecting continuing series of lots or batches, but may also be used for inspecting individual lots. Advises users to consult operating characteristic curves to find appropriate sampling plans. (A good discussion of this standard is found in *Quality Planning and Analysis*, Chapter 17, by J. M. Juran and F. M. Gryna, Jr., (McGraw-Hill, Inc., 1980).)

DEPARTMENT OF ENERGY (DOE):

Order 1324.2A, *Records Deposition*

Assigns responsibilities, establishes guidelines, and prescribes policies, procedures, and standards for the storage and disposition of records.

Order 1324.5, *Records Management System*

Describes the scope, personnel responsibilities, and operations of the DOE records management system.

Order 1330.1C, *Computer Software Management*

Establishes policies and guidelines for software development and for implementing a software management program. Identifies responsibilities and authorities from the contractor level up through the DOE hierarchy.

Order 2030.4A, *Reporting Fraud, Waste, and Abuse to the Office of the Inspector General*

Establishes policies and procedures for reporting fraud, waste, abuse, or corruption to the Department of Energy, Office of the Inspector General.

Order 4330.4A, *Maintenance Management Program (10 CFR 830.340)*

Provides general policy and objectives for establishing cost-effective maintenance and repair programs for DOE property and facilities.

Order 4700.1, *Project Management System*

Provides instructions, formats, and procedures for developing and implementing the DOE's project management system.

Order 5000.3B, *Occurrence Reporting and Processing of Operations Information*

Assigns responsibilities and provides guidelines for developing and implementing a system for occurrence reporting. Includes root cause analyses and a system for identifying and tracking corrective actions, sharing lessons learned, and conducting trend analyses.

Order 5400.5, *Radiation Protection for the Environment (10 CFR 834)*

Establishes basic policy for environmental protection in the area surrounding nuclear facilities.

Order 5480.GRD, *Graded Approach*

Establishes basic policy for applying the graded approach to the DOE's Office of Environment, Safety and Health and the Office of Safeguards and Security's requirements.

Order 5480.3A, *Hazardous Materials Packaging and Transportation Safety*

Assigns responsibility and authority and establishes requirements for safely packaging and transporting hazardous materials, including wastes.

Order 5480.4, *Environmental Protection, Safety, and Health Protection Standards*

Specifies environmental, safety, and health (ES&H) standards applicable to all DOE and DOE-contractor locations. Includes references to additional ES&H standards.

Order 5480.5, *Safety of Nuclear Facilities*

Establishes safety program requirements to ensure that nuclear facilities are sited, designed, constructed, modified, operated, maintained, and decommissioned in accordance with the codes and standards used at NRC-licensed nuclear facilities. Identifies requirements to ensure that radioactive and fissionable materials are produced, processed, stored, transferred, and handled in a manner that minimizes the probability that an accident will occur. Establishes requirements for an ES&H program and processes for reviewing ES&H concerns, identifying and reducing risks to acceptably low levels, documenting actions authorized by

management, and evaluating potential criticality hazards associated with handling fissionable material outside nuclear reactors.

Order 5480.6, *Safety of DOE-Owned Nuclear Reactors*

Establishes program requirements to ensure that the safety of each DOE-owned reactor has been analyzed, the analyses documented, and DOE notified of the findings. Identifies requirements for siting, design, construction, modification, operation, maintenance, and decommissioning reactors.

Order 5480.11, *Radiation Protection for Occupational Workers (10 CFR 835)*

Provides requirements and guidelines for radiation protection for nuclear facilities occupational workers..

Order 5480.19, *Conduct of Operations (10 CFR 830.310)*

Provides requirements and guidelines for developing directives, plans, and procedures to improve the quality and uniformity of operations at DOE facilities.

Order 5480.20, *Personnel Selection, Qualification, and Training, and Staffing Requirements at DOE Reactor and Non-Reactor Nuclear Facilities (10 CFR 830.330)*

Establishes selection, qualification, training, and staffing requirements for personnel who operate, maintain, and provide technical support for DOE-owned Category A and B reactors and non-reactor facilities.

Order 5480.21, *Unreviewed Safety Questions, (10 CFR 830.112)*

Order 5480.22, *Technical Safety Requirements, (10 CFR 830.320)*

Outlines the criteria, content, scope, format, approval process, and reporting requirements for technical safety requirements at DOE facilities.

Order 5480.23, *Safety Analysis Reporting, (10 CFR 830.110)*

Order 5481.1B, *Safety Analysis and Review System*

Establishes uniform requirements for preparing and reviewing safety analyses of DOE operations, including identifying and eliminating or controlling hazards, assessing risk, and documenting management's authorization.

Order 5482.1B, *Environment, Safety, and Health Appraisal Program*

Establishes the environment, safety, and health appraisal program for the DOE facilities and contractors.

Order 5700.6B, *Quality Assurance, Rev. II, (10 CFR 830.120)*

Provides requirements and assigns responsibilities for establishing, implementing, and maintaining QAPs for DOE programs.

Order 5700.6D, *Quality Management*

Replaces 5700.6C, Quality Assurance. Provides requirements and assigns responsibilities for establishing, implementing, and maintaining Management Plans for DOE programs.

Order 6430.1A, *General Design Criteria*

Defines design criteria for DOE facilities, systems, and operations.

QC-1, *Quality Criteria-1 (Nuclear Weapons Production)*

Establishes minimum requirements for the quality of operations at DOE facilities responsible for procuring or producing weapons and weapons-related material and software.

QC-2, *Quality Criteria-2 (Nuclear Weapons Research, Design, Development, and Testing)*

Establishes minimum requirements for the quality of nuclear weapons research, design, development, and testing.

DOE-ER-STD-6001-92, *Implementation Guide for Quality Assurance Programs for Basic and Applied Research*

Supplements Order 5700.6C. Provides guidance for implementing QAPs for research and development programs.

DOE-ER-1033, US-20-A-B & E, *Recommended Practices and Guidelines for Procurement of Magnetic Fusion Energy Electrical Equipment*

Defines standards for preparing procurement specifications for magnetic fusion energy electrical equipment.

G-830.120-REV.0, *Implementation Guide, for use with, 10 CFR PART 830.120 Quality Assurance*, April 15, 1994. This guide is intended specifically for use with 10 CFR 830.120. It is used as the model for the tabbed section of this guidebook. Like all guides it was meant to be generic and for Los Alamos needed to have the "Tips" section added to address specific Los Alamos situations.

DOE-ALBUQUERQUE (DOE-AL) ORDERS:

DOE-AL 54XA, *Operational Readiness Review (ORR) Program*

Establishes requirements for formal internal reviews to assess the operational readiness of an activity (facility, system, or process). The ORR process consists of two distinct reviews: an internal review by the contractor and a subsequent review by DOE.

DOE-AL 57XA, *AL Standards and Calibration Program*

Establishes minimum requirements for developing, implementing, managing, and operating a standards and calibrations program for use in nuclear weapons and non-weapons programs and in general operations.

ENVIRONMENTAL PROTECTION AGENCY (EPA):

EPA QAMS 004, *Guidelines and Specifications for Preparing QA Program Plans*

Establishes requirements for QAPs and specifications for environmental measuring programs.

EPA QAMS 005, *Interim Guidelines and Specifications for Preparing QA Project Plans*

Establishes requirements for environment-related QA project plans.

EPA QAMS 530, *Technical Guidance Document: Construction QA for Land Disposal Facilities*

Defines QA requirements for constructing land disposal facilities.

EPA QAMS 540, *Data Quality Objectives for Remedial Response Activities*

Defines data-quality objectives for remedial response activities.

AMERICAN NATIONAL STANDARDS INSTITUTE/AMERICAN SOCIETY OF MECHANICAL ENGINEERS (ANSI/ASME) STANDARDS:

N45.2-1977, *Quality Assurance Program Requirements for Nuclear Facilities*

Expands on Atomic Energy Commission QA regulations and provides guidance on developing detailed QA practices and procedures.

N45.2.10-1973, *Quality Assurance Terms and Definitions*

Defines the QA terms relevant to nuclear power plant construction.

NQA-1-1991, *Quality Assurance Program Requirements for Nuclear Facilities*

NQA-2-1989, *Quality Assurance Requirements for Nuclear Facilities Applications*

Discusses QA requirements for nuclear power plant operations.

NQA-3-1989, *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*

NOTE: The latest issue of NQA-1 was in 1994. It includes revisions of the former NQA-1 (Quality Assurance Requirements for Nuclear Facility Applications) as Part I, NQA-2 (Quality Assurance Requirements for Nuclear Facility Applications), as Part II, but not NQA-3, which will be included in a later version..

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA) STANDARDS:

NHB-5300.4, *Reliability and Quality Assurance Documents* (1A, 1B, 1C, 1D, 2, 2B, 3A.1, 3F, 3G, 3H, 3I, 3J)

NHB-5300.4 (1A), *Reliability Program Provisions for Aeronautical and Space System Contractors*

NHB-5300.4 (1B), *Quality Program Provisions for Aeronautical and Space System Contractors*

NHB-5300.4 (2B), *Quality Assurance Provisions for Government Agencies*

The rest are on quality assurance of specific tasks, such as soldering.

NHB 5330.7, *Management of Government Quality Assurance Functions for Supplier Operations*

Provides QA guidance for NASA suppliers and contractors at all NASA facilities.

ANSI/INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS (IEEE) STANDARDS:

Std 729-1983, *IEEE Standard Glossary of Software Engineering Terminology*

Defines terms common in computer software engineering.

Std 730-1984, *IEEE Standard for Quality Assurance Plans*

Defines requirements for Software Quality Assurance Plans (SQAPs).

Std 830-1984, *IEEE Guide to Software Requirements Specifications*

Establishes guidelines for writing software requirements specifications (SRSs).

Std 983-1986, *IEEE Guides to Software Quality Assurance Planning*

Provides guidance on preparing SQAPs. Supplements ANSI/IEEE Std. 730-1984.

INTERNATIONAL STANDARDS:

ISO-9000—9004, *Quality Management and Quality Assurance Standards and Guidelines for Selection and Use*

ISO-9000, Introduction

ISO-9001, Design/Development, Production, Installation, and Servicing

ISO-9002, Production and Installation (sub-section of ISO-9001)

ISO-9003, Final Testing (sub-section of ISO-9002)

ISO-9004, Internal Organizational Standards

Comprises five QA standards used by the European Community (EC). (A full ISO-9000 quality program consists of ISO-9000, ISO-9001, and ISO-9004.)

AMERICAN NATIONAL STANDARDS INSTITUTE/AMERICAN SOCIETY FOR QUALITY CONTROL (ANSI/ASQC) STANDARDS:

ANSI/ASQC D4-19XX, (to be issued), Quality Systems Requirements for Environmental Programs

TABBED SECTION REFERENCES:

- ¹ *Quality Assurance in Research and Development***, by George W. Roberts
- ² *Practical Reliability Engineering***, by Patrick D. T. O'connor, John Wiley & Sons, 1985.
- ³ *Out of the Crisis***, by W. Edwards Deming, MIT press, Cambridge, MA., 1982.
- ⁴ *Quality Planning and Analysis***, by J. M. Juran and Frank M. Gryna, Jr., McGraw-Hill, 1980.
- ⁵ *Personnel Management***, by Dr. Herbert J. Chruden and Dr. Arthur W. Sherman, Jr., South-Western Publishing Co., Cincinnati, OH, 1976.
- ⁶ *Dr. Deming, the American Who Taught the Japanese About Quality***, by Rafael Aguayo, Carol Publishing Group, New York, NY., 1990.
- ⁷ *Quality Assurance Guidebook, Rev. 0***, Quality Assurance Support Group, Los Alamos National Laboratory, 1993